

## REMARKS

Initially, the Examiner has rejected claims 42 and 49 under 35 U.S.C. 112, second paragraph, as being indefinite, apparently for providing no antecedent basis in claims 40 and 44 for the term “metronidazole” in claims 42 and 49, respectively. However, it is not apparent to Applicant why antecedent basis of metronidazole should be required in claims 40 and 44, inasmuch as metronidazole is a further antibiotic optionally included in addition to azithromycin. Thus, Applicant believes the Examiner may have misinterpreted the claim. Metronidazole does not have antecedent basis in claims 40 and 44 since it may or may not be present in these claims. Applicant has, however, amended claims 42 and 49 to add the word “further” which is believed to make the claims perhaps more clear, but has not changed the scope of the claims from their original scope. Moreover, no new issues are raised by these amendments and no new searches would be necessary, so Applicant believes the amendments to the claims, which lower the number of issues for appeal, should be entered, and respectfully requests that these amendments be entered.

With respect to the prior art rejection, the Examiner has rejected claims 40-54 under 35 U.S.C. 103(a) as being unpatentable over Herschler et al. (US Patent No. 4,997,823) in combination with Kelly (International Publication No. WO 02/092087) and Kirschner et al. (US Patent No. 6,899,890). In response, Applicant respectfully traverses this rejection.

In response to a previous Office Action, Applicant noted that neither Herschler, et al., nor Kelly, et al., discloses the vaginal administration of azithromycin. Thus, in the present Office Action, the Examiner alleges that Kirschner, et al., discloses the vaginal administration of azithromycin, and combines it with Herschler et al. and Kelly et al. Applicants respectfully disagree with this allegation.

In this respect, Kirschner, et al., discloses an essentially pH neutral vaginal drug delivery system suitable for modified delivery of a therapeutically active material in the vaginal cavity. Kirschner, et al., refers to a long list of many therapeutically active drugs for administration such as antifungal agents, antiviral agents, spermicides, surface active drugs, androgenic substances, for use with a wide selection of delivery systems such as dispersions, solids, suspensions, ointments, pastes, powders, foams, creams, jellies, sprays,

gels, tablets, sponges and patches. The only specific examples give by Kirschner, et al, concern drug delivery systems containing metronidazole and/or clindamycin.

Reference to azithromycin in Kirschner, et al., is limited to a passing mention in a long list of many other antibacterial agents as part of a larger list of many therapeutically active drugs. Kirschner, et al., does not provide any examples or details as to how a drug delivery system containing azithromycin may be formulated or administered. Thus, one of ordinary skill in the art would not have been able to combine the references to provide for the administration of azithromycin vaginally with prostaglandins in order to treat various pelvic infections. There is simply no teaching or suggestion of that in any of the references and/or in any combination of the references, that azithromycin and a prostaglandin can be administered vaginally. Even if the Examiner takes the position that Kirschner et al. provides for the vaginal administration of azithromycin, it does not provide for the vaginal administration of BOTH azithromycin and a prostaglandin. Simply asserting that it would have been obvious to do so can only be done in hindsight and would not be viewed by one of skill in the art as “expected” prior to Applicant’s invention.

The formulation and administration of drugs for vaginal use is not a simple matter. It is not straightforward to merely substitute drugs which are known as vaginal administration with other new drugs unknown for vaginal administration. Thus, just because one antibiotic may be suitable for vaginal administration, namely metronidazole in the present case, this does not make it obvious or straightforward to administer all antibiotics vaginally. A person of ordinary skill in the art would not expect to administer all antibiotics vaginally with any beneficial purpose in mind, let alone, to treat pelvic tissue infections.

The disclosure of the vaginal administration of azithromycin in Kirschner, et al., is not enabled, in that it would not be possible for a person of ordinary skill in the art to formulate and administer azithromycin vaginally from the limited teaching of Kirschner, et al., and it would, furthermore, not be possible for a person of ordinary skill in the art to formulate and administer azithromycin *with a prostaglandin* vaginally. Therefore, it would not be obvious to reach the present invention from a combination of Kirschner, et al., with

Herschler, et al., and/or Kelly, et al., since none of these documents teaches how to administer azithromycin vaginally.

It has been found in the present invention that co-administration of antibiotic and prostaglandin, or administration of prostaglandin followed by antibiotic, is advantageous because of a synergistic effect between the antibiotic and prostaglandin. In this way, the collagenolytic properties of prostaglandin helps to break apart collagen in the tissue at the site of administration and allows for easier absorption of antibiotic into the target tissue. Thus, the treatment of pelvic tissue infection is improved.

In light of the foregoing, reconsideration of all pending claims 40-54 is respectfully requested, and a Notice of Allowance of those claims is earnestly solicited. Should the Examiner wish to discuss any of the foregoing in greater detail, the undersigned attorney would welcome a telephone call.

In the event that a fee required for the filing of this document is missing or insufficient, the undersigned attorney hereby authorizes the Commissioner to charge payment of any fees associated with this communication or to credit any overpayment to Deposit Account No. **18-0987**.

Respectfully submitted,



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